

Notice of Allowability

Application No.

10/661,430

Applicant(s)

CUMMINGS ET AL.

Examiner

Art Unit

Nashaat T. Nashed, Ph. D.

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/12/03.
2. ☒ The allowed claim(s) is/are 5-9, 11, 12, 17, 19 and 23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 6/4/04 & 5/12/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Nashaat T. Nashed, Ph. D.
Primary Examiner
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The application has been amended as requested in the communications filed February 21, 2006 and March 3, 2006. Claims 1-4, 10, 13-16, 18 and 20-22 have been canceled, claims 5, 8, 9, 11-12, 17, and 19 have been amended, and new claim 23 has been entered.

Claims 5-9, 11, 12, 17, 19, and 23 are pending and under consideration.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher W. Corbett on March 8, 2006.

The application has been amended as follows:

- Claim 5 An isolated polynucleotide which encodes a protein having β 4 acetylgalactosaminyl transferase activity of SEQ ID NO: 1 and lacking the transmembrane domain of residues 7-29 of SEQ ID NO: 1, ~~polynucleotide absent a nucleotide sequence which encodes the transmembrane domain of residues 7-29 of SEQ ID NO: 1~~ wherein the polynucleotide encodes a soluble β 4 acetylgalactosaminyl transferase.
- Claim 12 The host cell of claim 8 transformed or transfected with an expressible polynucleotide encoding a peptide or polypeptide requiring post-translational formation of the a ~~GalNAc β 1,4GlcNAc~~ GalNAc β 1-4GlcNAc structure thereon.
- Claim 17 A method for producing a protein or peptide having a the GalNAc β 1-4GlcNAc ~~GalNAc β 1,4GlcNAc~~ structure thereon, comprising the steps of: providing a host selected from the group consisting of an isolated animal cell, a fungal cell, an insect cell, and a plant cell, said host cell comprising an expression vector comprising a polynucleotide encoding a peptide or polypeptide requiring a the GalNAc β 1-4GlcNAc ~~GalNAc β 1,4GlcNAc~~ structure and the vector comprising a polynucleotide comprising SEQ ID NO:2; and culturing ~~expressing~~ the host cell thereby forming a glycosylated protein or peptide having the ~~GalNAc β 1,4GlcNAc~~ GalNAc β 1-4GlcNAc structure comprising a β -1-4 ~~β -1,4~~ linkage between the GalNAc and the GlcNAc.
- Claim 19 The method of claim 17 wherein the β 4 acetylgalactosaminyl transferase comprises SEQ ID NO: 1.

Claim 23 A method of glycosylating a substrate comprising a terminal β -linked GlcNAc moiety to form the structure GalNAc β 1-4GlcNAc~~protein or peptide~~, comprising:
providing a β 4 acetylgalactosaminyl transferase comprising SEQ ID NO:1;
and
contacting ~~exposing~~ the β 4 acetylgalactosaminyl transferase ~~to~~ with said substrate ~~the protein or peptide~~ and UDPGalNAc thereby forming a GalNAc β 1,4GlcNAc GalNAc β 1-4GlcNAc ~~structure thereon~~, wherein GalNAc β 1,4GlcNAc GalNAc β 1-4GlcNAc ~~structure~~ comprising a β 1-4 ~~β 1,4~~ linkage between the GalNAc and the GlcNAc.

Claims 5-9, 11, 12, 17, 19, and 23 are allowed.

The following is an examiner's statement of reasons for allowance: The application discloses the nucleic acid of SEQ ID NO: 1 encoding the β 4 acetylgalactosaminyl transferase of SEQ ID NO: 1. Also, application teaches the water-soluble enzyme, which is missing the trans membrane domain of amino acid residues 7-29 of SEQ ID NO: 1. Applicants enable the use of the membrane bound and water soluble enzyme to make GalNAc β 1-4GlcNAc. The nucleic acid encoding a probable galctosyl transferase from *Caenorhabditis elegans* of the amino acid sequence of SEQ ID NO: 1 and the amino acid sequence itself are known in the prior art (Science 12/11/1998, Vol. 282, page 2012, Database: Uniprot, accession number Q9GUM2, and Dtabase: Genbank, Accession AC025727). The prior art, however, does not disclose the trans membrane domain of residues 7-29, the particular deletion of residues 7-29 from SEQ ID NO: 1 renders the enzyme water soluble, or that the enzyme is β 4 acetylgalactosaminyl transferase. The specification teaches that the enzyme is highly selective for transferring UDPGalNAc, and UDPGal is about 1% as reactive as UDPGalNAc in the transfer reaction catalyzed by said transferase, see Table 2 at page 43. Thus, the prior art does not anticipate or render obvious the nucleic acid encoding the soluble protein consisting of the deletion mutants of residues 7-29 of SEQ ID NO: 1, or the use of the deletion mutant or the wild-type enzyme in the synthesis of GalNAc β 1-4GlcNAc.

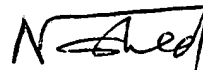
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656